

K113624

TABLE 4

SUMMARY

1. Date the summary was prepared: March 1, 2012
2. Submitter's name: Guangzhou Wondfo Biotech Co., Ltd.
Address: South China University of Technology
Guangzhou, P.R. China 510641
Phone: 012-86-20-32296069

MAR 12 2012

Name of contact person: Joe Shia
LSI International, Inc.
504 East Diamond Ave.,
Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
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3. Name of the device

Common or usual name: Buprenorphine Urine Test
Oxycodone Urine Test
Trade or proprietary name: Wondfo Buprenorphine Urine Test
Wondfo Oxycodone Urine Test

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
DJG	21 CFR 862.3650
DJG	21 CFR 862.3650

4. The legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

1. Acon Laboratories, Inc. Acon BUP One Step Buprenorphine Test Strip and Acon BUP One Step Buprenorphine Test Device, K060466.
2. Acon Laboratories, Inc. Acon OXY One Step Oxycodone Test Strip and Acon OXY One Step Oxycodone Test Device, K033047

5. Description of the device:

Assay Principle: Immunochromatograph assay for Buprenorphine and Oxycodone Urine Test using a lateral flow, one step system for the qualitative detection of Buprenorphine, Oxycodone(target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

6. Intended use of the device:

Wondfo Buprenorphine Urine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a cutoff concentration of 10 ng/mL. The test is available in a dip card

format and a cup format. For in vitro diagnostic use only. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Wondfo Oxycodone Urine Test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a cutoff concentration of 100 ng/mL. The test is available in a dip card format and a cup format. For in vitro diagnostic use only. This product is intended for over-the-counter and prescription use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

7. Comparison to the predicate device

A summary comparison of the features of the Wondfo Buprenorphine Urine Test and Wondfo Oxycodone Urine Test and the predicate devices is provided in the Table 1 & Table 2.

Table 1: Features comparison of Wondfo Buprenorphine Urine Test and the predicate device

Item	Device	Predicate - K060466
Indication(s) for use	For the qualitative determination of Buprenorphine in human urine.	Same
Calibrator	Buprenorphine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Specimen Type	Human urine	Same
Cut Off Values	10 ng/ml	Same
Configurations	Cup, dip card	Strip, Device
Intended Use	Prescription Use	Same

Table 2: Features comparison of Wondfo Oxycodone Urine Test and the predicate device

Item	Device	Predicate - K033047
Indication(s) for use	For the qualitative determination of Oxycodone in human urine.	Same
Calibrator	Oxycodone	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on	Same

	the principle of antigen antibody immunochemistry.	
Type Of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Specimen Type	Human urine	Same
Cut Off Values	100 ng/ml	Same
Configurations	Cup, dip card	Strip, Device
Intended Use	OTC Use & Prescription Use	Prescription Use

The Wondfo Buprenorphine Urine Test and the Wondfo Oxycodone Urine Test have similar technological characteristics and performances to the predicates. The Wondfo test devices and predicates are equivalent.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Guangzhou Wondfo Biotech Co., Ltd
c/o Mr. Joe Shia
504 East Diamond Ave, Suite F
Gaithersburg, MD 20878

MAR 12 2012

10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: k113624
Trade Name: Wondfo Buprenorphine Urine Test, Wondfo Oxycodone Urine Test
Regulation Number: 21 CFR §862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Codes: DJG
Dated: February 22, 2012
Received: February 27, 2012

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

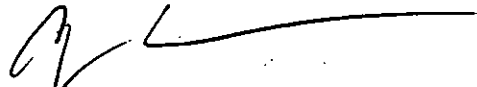
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>

Sincerely yours,



Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k113624

Device Name: Wondfo Buprenorphine Urine Test

Indications for Use:

Wondfo Buprenorphine Urine Test is an immunochromatographic assay for the qualitative determination of Buprenorphine in human urine at a cutoff concentration of 10 ng/mL. The test is available in a dip card format and a cup format. For in vitro diagnostic use only. This product is only intended for prescription use and is not intended for point-of-care use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K113624

Indications for Use Form

510(k) Number (if known): k113624

Device Name: Wondfo Oxycodone Urine Test

Indications for Use:

Wondfo Oxycodone Urine Test is an immunochromatographic assay for the qualitative determination of Oxycodone in human urine at a cutoff concentration of 100 ng/mL. The test is available in a dip card format and a cup format. For in vitro diagnostic use only. This product is intended for over-the-counter and prescription use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

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Evaluation and Safety

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